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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.												
10/689,628	10/22/2003	Kenneth M. Adams	2401.142-US	4034												
7590 Epstein & Gerken Suite 340 1901 Research Blvd Rockville, MD 20850		08/07/2007	<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">DOWE, KATHERINE MARIE</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>3734</td><td></td></tr><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>08/07/2007</td><td>PAPER</td></tr></table>		EXAMINER		DOWE, KATHERINE MARIE		ART UNIT	PAPER NUMBER	3734		MAIL DATE	DELIVERY MODE	08/07/2007	PAPER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/689,628	Applicant(s) ADAMS, KENNETH M.	
	Examiner Katherine M. Dowe	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a complete response to the amendment filed 4/12/2007.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the inner tube has "an inner diameter the same size as the inner diameter of an elongate inner tube forming the inner tubular member of a straight tissue cutting instrument of the same diametric size as the angled tissue cutting instrument" (lines 5-7). Furthermore the claim recites the outer tubular member has "an outer diameter the same size as the outer diameter of a straight outer tubular member of the straight tissue cutting instrument of the same diametric size as the angled tissue cutting instrument" (lines 18-21). The diametric size of the straight tissue cutting instrument is not defined and thus, the limitation does not provide any structural limitations.

4. Claims 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the inner tube has an inner diameter of same size as the inner diameter of an inner tubular member of a 2.9 mm, 3.5 mm, and 4.0 mm straight tissue cutting instrument respectively. However, the inner

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diameter of each straight tissue cutting instrument is not recited. Thus, the claims do not provide any size limitations.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-10 and 12-13, 15-19, and 21 of U.S. Patent No. 6,656,195 in view of Aznoian et al. U.S. Patent No. 5,908,381. Although the conflicting claims are not identical, they are not patentably distinct from each other. The patent and the instant application are claiming common subject matter including: a flexible inner tube rotatably disposed within an outer tube; the inner tube being of solid construction with a helical cut in a first direction and a spiral wrap disposed over the

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helical cut in a second opposite direction; a cutting configuration and a cutting port disposed on the inner and outer tubes respectively; and an aspiration passage.

Although, a plurality of bends is not claimed in the patent, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a plurality of bends to enable the surgeon to better manipulate the instrument (see Aznoian). Furthermore, the specifics of the stepped pattern are considered obvious design choices, as applicant failed to specify that these were critical in any way, failed to state how these limitations solved any particular problem, or were for any particular purpose, and the Examiner contends that any difference in the specifications claimed by the patent with respect to the above limitations would have performed equally as well as the specific claim limitations of the instant application.

7. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6-16, and 20-22 of U.S. Patent No. 6,533,749 in view of Aznoian et al. U.S. Patent No. 5,908,381. Although the conflicting claims are not identical, they are not patentably distinct from each other. The patent and the instant application are claiming common subject matter including: a flexible inner tube rotatably disposed within an outer tube; the inner tube being of solid construction with a helical cut in a first direction and a spiral wrap disposed over the helical cut in a second opposite direction; a cutting configuration and a cutting port disposed on the inner and outer tubes respectively; and an aspiration passage. Although, a plurality of bends is not claimed in the patent, it would have been obvious to

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one of ordinary skill in the art at the time of the invention to provide a plurality of bends to enable the surgeon to better manipulate the instrument (see Aznoian). Furthermore, the specifics of the stepped pattern are considered obvious design choices, as applicant failed to specify that these were critical in any way, failed to state how these limitations solved any particular problem, or were for any particular purpose, and the Examiner contends that any difference in the specifications claimed by the patent with respect to the above limitations would have performed equally as well as the specific claim limitations of the instant application.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 6, 7, 9-11, and 14-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Peters et al. (US 2002/0038129). Peters et al. disclose an angled tissue cutting instrument (Figs 1-9) comprising outer and inner tubular members (12 and 14). The inner tubular member a continuous helical cut (39) formed in a step pattern at an angle in a first direction to impart flexibility (para 0033-0034) and a cutting configuration (70) at the distal end. A cutting port (28) disposed on the outer tubular member exposes the cutting configuration (para 0044). A single layer of spiral wrap (68) is disposed over the helical cut at the same angle in an opposite direction and ends of the

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spiral wrap are secured to the inner tubular member (para 0039). An aspiration passage extends through the inner tube (para 0042) and an aspiration port (88) is disposed at the distal end of the inner tube. The stepped pattern of the helical cut comprises a transverse cut segment (Fig 12 – from corners 355 to 355) and a longitudinal cut segment (from corners 355 to 359) where the transverse segment extends at a 20 degree angle relative to a plane perpendicular to the longitudinal axis (para 0053).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (US 2002/0038129), as applied to claim 1 above, in view of Aznoian et al. (US 5,908,381). Peters et al. disclose the invention substantially as claimed including a

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bend (22) in the outer tubular member. Furthermore, Peters et al. disclose the dimensions, location, and direction of the bend are dependent upon the procedure to be performed and the location of the operative site to be accessed (para 0032). However, Peters et al. do not disclose the instrument specifically comprises a plurality of bends. Aznoian et al. discloses disclose a similar endoscopic instrument with a plurality of bends that extend in different directions at different angles (Fig 1, elements 50 and 52), where the proximal bend (52) is bent at a first angle of 45 degrees from the proximal length portion and the distal bend (50) is bent in a second direction opposite the proximal bend at a second angle of 15 degrees from the intermediate length portion (col 6, lines 39-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Peters et al. such that the outer tubular member comprised a second bend that extends in a different direction at a different angle, such that the proximal bend is bent at a first angle of 45 degrees from the proximal length portion and the distal bend is bent in a second direction opposite the proximal bend at a second angle of 15 degrees from the intermediate length portion. Thus, the instrument would be easier for the surgeon to manipulate around tortuous paths. Furthermore, it would be obvious to modify the device of Peters et al. to include a plurality of helical cuts and single layers of spiral wrap along the additional length portions created with the additional bends because Peters et al. teaches the helical cuts and the spiral wrap enhance the function of the cutting instrument and impart flexibility at the bends (para 0012).

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12. Claims 8, 12, 13, and 22 rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (US 2002/0038129), as applied to claims 7, 9, 14, and 16 above.

Peters et al. disclose the invention substantially as claimed as shown above. However, Peters et al. do not disclose the dimensions of the rotational intervals or the length of the transverse and longitudinal cut segments. Applicant has not disclosed that having the steps repeat at rotational intervals of 100 degrees or having the length of the transverse segment greater than the length of the longitudinal segment solves any stated problem or is for any particular purpose. Moreover, it appears the stepped pattern of Peters et al., or applicant's invention, would perform equally well with the stepped pattern repeating at any rotational interval and comprising any ratio of cut segment lengths. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Peters et al. such that the stepped pattern repeated at rotational intervals of 100 degrees about the central longitudinal axis and comprised a longer transverse cut segment than longitudinal cut segment because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Peters et al.

13. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (US 2002/0038129), as applied to claim 14 above, in view of Applicant's disclosure. Peters et al. disclose the invention substantially as claimed as shown above. However, Peters et al. do not disclose the ideal diametric sizes of the angled tissue cutting instrument. The applicant discloses "angled tissue cutting

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instruments are commonly available in the same diametric sizes as straight tissue cutting instruments, and representative standard diametric sizes for angled tissue cutting instruments include 2.9 mm, 3.5 mm, 4.0 mm, and 4.5 mm" (page 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a standard in the art using readily available sizes and modify the device of Peters et al. such that the inner tubular diameters were 2.9 mm, 3.5 mm, or 4.0 mm.

Response to Arguments

14. Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
July 31, 2007


(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER
8/31/07